

## **REMARKS**

### **I. OVERVIEW**

This amendment accompanies a request for continued examination.

Claims 1, 2, 5-11, and 13-23 have been rejected. Claims 1, 2, 5-11, and 13-23 are newly rejected under 35 U.S.C. §112, first paragraph, as allegedly necessitated by amendment. Claims 1, 2, 5 and 9 have been amended and claim 12 cancelled pursuant to the Examiner's Final Office Action. Claim 15 has been amended to correct a typographical error.

### **II. ELECTION/RESTRICTIONS**

The Examiner has required that a complete reply to the final rejection requires cancellation of nonelected claim 12. Claim 12 has been cancelled.

### **III. CLAIM OBJECTIONS**

The Examiner has objected to claims 1, 2, and 5 containing the language "at least one carbohydrate and electrolytes" in line 5 of claim 1 and line 5 of claim 2. The Applicant has changed the claim language to "at least one carbohydrate and further comprising electrolytes" as requested by the Examiner. The Examiner objected to the term "claims" in line 1 of claim 5 and requested it be changed to "claim." This has been changed. The Examiner also objected to claim 2 as it recites a method of making a composition and then recites a method of using a composition. The Applicant has amended claim 2 to recite a solely method of using the composition to treat gastrointestinal disorders of monogastric animals pursuant to the Examiner's objection.

The objection to "monogastric disorder", as being broader than the disclosed therapeutic treatment of diarrhea has been obviated by amending to a diarrhea treatment.

### **III. CLAIM REJECTIONS UNDER 35 U.S.C. §112, ¶ 1**

The Examiner has newly rejected claims 1, 2, 5-11 and 13-23 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and provide support or antecedent basis for "A composition for treatment of gastrointestinal disorders of monogastric animals" in claim 1, "feeding the prepared composition to animals" in claim 2, "a mixture of at least one carbohydrate and electrolyte" in claims 1 and 2, and "derived from" in line 2 of claim 9. (7/27/07 Office Action, p. 7).

The Examiner states that the previously amended claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. First, the Examiner states that the amendments to claims 1 and 2 introduces both an intended use and a mixture not previously disclosed in the claims and does not have support in the specification. Then the Examiner stated that the amendment to claim 2 of "feeding the prepared composition to animals" presents an additional step not previously disclosed in the claims and which does not have support in the specification. Additionally, the Examiner stated that the amended claim 9 with the limitation "wherein at least one amino acid is derived from the soluble components of lactic yeast," claims a completely different invention, and is therefore also considered new matter. (7/27/07 Office Action, p. 7).

The Applicant has clarified Claim 9, rendering the objection moot.

The Examiner stated that the Applicant must particularly point to the specification for literal support. (7/27/07 Office Action, p. 8). The Applicant first points out that the amendments to the claims are supported by the original claims themselves, which is to be considered in 35 U.S.C. §112 rejections. Moreover, the in vitro experimentation of Isphagula Husk on cell growth, as described on pages 16-20 of the original specification, illustrates its use in combination with a carbohydrate and electrolyte. Specifically, the compositions of the components show the electrolytes Ca, Na, K, and Cl use in multiple variations with sugars (carbohydrates) contained in Protibel ("lactic yeast", "Milchhefe"). Additionally, the listing of ingredients contained in the composition of Example 1 on page 23 of the original description, show yet another composition disclosed and enabled by the original specification containing a mixture of a carbohydrate and an electrolyte. The Examiner has already appreciated that Applicant has disclosed examples of the compositions having the intended effects of treating gastrointestinal disorders of monogastric animals, enhancing cell growth of the intestinal epithelium, and the various objects of the invention. Therefore, there is no new matter as the Applicant has shown literal support in the as-filed specification and specific examples showing possession of the concept for the method, mixture, and source of amino acids.

#### **IV. CLAIM REJECTIONS UNDER 35 U.S.C. §112, ¶ 2**

The Examiner's 35 U.S.C. §112, ¶ 2 objections have been rendered moot by the amendment to claim 9, providing proper antecedent basis to specification page 10, lines 1-25, and the amendment to claims 1 and 2, clarifying what Applicant intends by "gastrointestinal disorders of monogastric animals," i.e., a diarrhea treatment.

## V. CLAIM REJECTIONS UNDER 35 U.S.C. §103

Newly amended claims 1, 5, 11, 13, 17, 21 and 23, and claims 6-8, 10, 14-16 and 18-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gjerlov (U.S. Patent No. 5,038,396), in view of Simone (U.S. Patent No. 5,397,786). The Examiner states that "Gjerlov does not (*emphasis added*) teach a composition comprising Isphagula Husk, at least one amino acid, at least one carbohydrate and electrolyte . . . further comprising glutamine, glucose, or alpha tocopherol." (7/27/07 Final Office Action, p. 11). The Examiner nevertheless then claims that it would be obvious to one of ordinary skill in the art to modify the compositions taught by Gjerlov and Simone to arrive at the claimed invention.

Even looking at the broadest composition claim 1, it requires 5-30% Isphagula Husk, 1-20% amino acid, and 20-80% of a mixture of at least one carbohydrate and electrolytes. Gjerlov, which is licensed to the assignee, represented the starting point for the present invention. What is missing from Gjerlov, and unexpected is the amino acid and Isphagula Husk advance cell growth and thus repair to treat diarrhea more than either alone [0061]. It therefore represents the classic case of the combination exceeding the sum of its parts. A possible mechanism for this is explained at [0062].

The Supreme Court recently articulated that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed. KSR Int'l Co. v. Teleflex, Inc., 82 U.S.P.Q.2d 1385, 1396 (2007). The Supreme Court only found a patent to be invalid as obvious after "convincing evidence" of obviousness was provided. Id. at 1400. No such convincing evidence has been provided by the Examiner, and therefore, the Examiner's

§103 rejection should be withdrawn absent convincing evidence that it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the compositions taught by Gjerlov and Simone. This case is like the Adams battery case, an unexpected result, more than additive is achieved by the combination.

In addition to the Examiner's failure to provide convincing evidence to support an obviousness rejection, the Examiner has overlooked the teaching in the prior art to maximize the intumescent content of a composition to treat diarrhea. Isphagula Husk is an intumescent agent capable of absorbing water, decomposing lactose and non-specifically binding mucopolysaccharides and bacteria cell walls. (Specification, p. 3, paragraph 29). Gjerlov teaches compositions containing Isphagula Husk for rehydrating monogastric animals, and Simone specifically teaches rehydration of humans using carbohydrates, electrolytes, amino acids, and at least one antioxidant. Specifically, Gjerlov teaches a composition for rehydrating monogastric animals containing 20-70%, but preferably 43% Isphagula Husk as an intumescent. (Column 5, lines 1-3). Simone does not teach the use of Isphagula Husk in any proportion for a composition to treat diarrhea, and no one teaches the unexpected result of the combination.

The Examiner states that it would have been obvious to "modify the composition taught by Gjerlov to include the ingredients of the composition taught by Simone to provide the instantly claimed invention at the time the invention was made since both compositions were known to rehydrate humans suffering from diarrhea." (7/27/07 Final Office Action, p. 12). This is inconsistent with the Examiner's appreciation that the cited references do not disclose compositions capable of successfully treating the symptoms of gastrointestinal disorders as referenced on page 11 of the Office Action. A composition

containing as little as 5-30% by weight of Isphagula Husk, in combination with the other elements of claim 1, is therefore not suggested by the prior art. Unexpected results and surprising experimental outcomes demonstrate that those skilled in the art at the time of the invention could not have had any reasonable expectation of success as the Examiner suggests (7/27/07 Final Office Action, p. 11), rendering the §103(a) rejection moot.

## VI. CONCLUSION

This amendment accompanies the filing of a Request for Continued Examination (RCE). Please charge Deposit Account No. 26-0084 the amount of \$405.00 for the RCE per the attached transmittal. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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